DEC 0 7 2001

Attachment 7 - 510(k) Summary

K013686

1. Company Identification

Eastman Kodak Company
Health Imaging Division
1669 Lake Avenue
Rochester, NY 14652
Establishment Registration: 1317267

2. Official Correspondent

Judith A Wallace
Regulatory Affairs
716 724-6111

3. Device Name

Trade Name: KODAK DirectView Tabletop CR Cassette

Common Name: Storage Phosphor Cassette

4. Device Classification

Class II

5. Applicable Standards

CEI IEC 60406 Ed. 3.0:1997 Cassettes for medical X-ray diagnosis – Radiographic cassettes and mammographic cassettes

ISO 4090 Photography – Film dimensions – Medical radiography

6. Intended Medical Use:

KODAK DirectView Tabletop CR Cassette holds a Storage Phosphor screen so the screen can be exposed by radiographic equipment for the recording of a patient radiation pattern. The screen is removed from the cassette and the pattern read in a laser phosphor digitizer.

7. Description of Device:

The device is a cassette for holding a storage phosphor screen. It is a standard x-ray diagnostic cassette used for film screen radiography that has been modified as follows. In

place of the two intensifying screens two pieces of black polycarbonate sheet are mounted on the foam presently used in the X-Omat Cassette. The storage phosphor screens is constrained by the film pocket of the cassette and held in place by the two plastic sheets when the cassette is closed.

8. Substantial Equivalence

The Kodak DirectView Tabletop CR cassette is basically a standard, screen-film diagnostic cassette that has been adapted to hold a storage phosphor screen. This device is identical in function and thus substantially equivalent to the cassettes associated with computed radiography systems marketed by Eastman Kodak Company, Fuji Medical Systems USA and Agfa Medical Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Ms. Judith A. Wallace
Regulatory Affairs Manager
Health Imaging Division
Eastman Kodak Co.
1669 Lake Ave.
ROCHESTER NY 14652

Re: K013686
Trade/Device Name: Kodak DirectView Tabletop Cassett
Storage Phosphor Cassette
Regulation Number: 21 CFR 892.1850
Regulation Name: Radiographic film cassette
Regulatory Class: II
Product Code: 90 IXA
Dated: November 2, 2001
Received: November 7, 2001

Dear Ms. Wallace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 5 – Indications for Use

510(K) Number (if known): K013686

Device Name: KODAK DirectView Tabletop CR Cassette

Indication of use: KODAK DirectView Tabletop CR Cassette holds a Storage Phosphor screen so the screen can be exposed by radiographic equipment for the recording of a patient radiation pattern. The screen is removed from the cassette and the pattern read in a laser phosphor digitizer.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013686